

Claims

1. Drain suitable for draining a human or animal antrum, organ or tissue, characterized in that it comprises an elastic biocompatible, biodegradable synthetic polymer, which polymer has at least one softening point (glass transition temperature) of at most mammalian body temperature.
2. Drain according to claim 1, which essentially entirely consists of said synthetic biodegradable polymer.
3. Drain according to any of the previous claims, wherein the polymer has at least one softening point (glass transition temperature) of at most 37 °C.
- 10 4. Drain according to any of the previous claims, wherein the biodegradable polymer comprises a polyester, polycarbonate, polyester-carbonate, polyanhydride, polyurethane and/or polyamide which are optionally combined with polyether groups.
5. Drain according to claim 4, wherein:
  - 15 - the polyester is selected from lactide polyester,  $\epsilon$ -caprolactone polyester, glycolide polyester, or copolymers thereof; and/or
  - the polyether is selected from polyethyleneglycol, polypropyleneglycol, copolymers thereof and polytetramethyleneoxide (PTMO).
6. Drain according to claim 5, wherein the polyester is a random DL-Lactide- $\epsilon$ -caprolactone copolyester, preferably having a lactide content of 20-75 mol %, more preferably 55-70 mol%, most preferably 62-69 mol%.
7. Drain according to claim 6, wherein the fraction of the L-enantiomer or the D-enantiomer of the lactide is from 65-95mol%, preferably from 70-90 mol%, more preferably about 85 mol%.
- 25 8. Drain according to claim 4, wherein the polyester, polyester-carbonate and/or polyanhydride is a segmented or block copolymer with randomly or alternating segments or blocks and consisting of at least two blocks with different composition.

9. Drain according to claim 8, wherein the segments or blocks are phase separated hard and soft segments, characterized by at least two phase transitions, one of them being a glass transition temperature lower than 37 °C, the other a glass transition temperature or melting temperature higher than  
5 37 °C.
10. Drain according to claim 8 or 9, wherein the segments or blocks forming the low temperature transition phase are composed of pre-polymers of (mixtures of) cyclic or non-cyclic monomers lactide, glycolide,  $\epsilon$ -caprolactone,  $\delta$ -valerolactone, trimethylenecarbonate, tetramethylenecarbonate, 1,5-  
10 dioxepane-2-one, para-dioxanone and/or hydroxyalkanoic acid.
11. Drains according to claim 8-10, wherein the copolymer or pre-polymers are obtained by a ring opening polymerisation initiated by a diol or di-acid compound.
12. Drains according to claim 8-11, wherein the pre-polymers forming  
15 the segments are linked by a difunctional aliphatic compound, preferably a diisocyanate, more preferably 1,4-butanediisocyanate.
13. Drain according to claims 9-12, wherein the segment or block with highest temperature phase transition (hard segment or block) is formed by poly-caprolactone, poly-valerolactone, poly-lactide, poly(lactide-glycolide), poly-  
20 para-dioxanone, poly(hydroxybutyric acid), polysebacic acid, poly(dodecanedioic anhydride) pre-polymers, and combinations thereof.
14. Drain according to claim 4, wherein the biodegradable polymer comprises a polyurethane, which biodegradable polymer is a phase separated copolymer with a polyester, polyester-carbonate and/or polycarbonate soft  
25 segment and a urethane hard segment with uniform block length.
15. Drain according to claim 14, wherein the polyurethane is formed by diisocyanate linked pre-polymer and diol components having the formula  $[-A-B-C-B-]_n$ , wherein A denotes the pre-polymer moiety, B denotes the diisocyanate moiety, C denotes the diol moiety, having a uniform block length;  
30 and n represents an integer larger than 1.

16. Drain according to claim 15, wherein the diol component is a linear aliphatic diol (X) with general structure  $\text{HO}-(\text{CH}_2)_n\text{-OH}$  with  $n = 2-8$  or  $\text{HO}-(\text{CH}_2\text{CH}_2\text{-O-CH}_2\text{CH}_2)_n\text{-OH}$  with  $n = 2-8$  or the diol (XYX) is a reaction product of two moles of the diol (X) with said diisocyanate.
- 5 17. Drain according to claim 15 or 16, wherein the diisocyanate is 1,4-butanediisocyanate
18. Drain according to claim 15-17, wherein the pre-polymer is formed by ring opening polymerisation initiated by a diol or polyethyleneglycol compound of the cyclic monomers lactide, glycolide,  $\epsilon$ -caprolactone,  $\delta$ -  
10 valerolactone, trimethylenecarbonate, tetramethylenecarbonate, 1,5-dioxepane-2-one and/or para-dioxanone.
19. Drain according to claim 14-18, wherein the polyester is a poly(DL-lactide- $\epsilon$ -caprolactone) and the diol compound is the reaction product of two moles of 1,4-butanediol and one mole of 1,4-butanediisocyanate.
- 15 20. Drain according to claim 14-18, wherein the polyester is a poly(DL-lactide- $\epsilon$ -caprolactone) and the diol compound is the reaction product of two moles of diethyleneglycol and one mole of 1,4-butanediisocyanate.
21. Drain according to claim 14-19, wherein the soft segment is a combination of a pre-polymer with a polyether pre-polymer, preferably a  
20 polyethyleneglycol.
22. Drain according to claim 21 wherein the polyethyleneglycol has a molecular weight of 1500.
23. Drain according to claim 14-18, wherein the polyurethane contains 1-25 wt.% polyethyleneglycol, preferably 5-15%, being present as a pre-  
25 polymer initiator, and the polyester is a poly(DL-lactide- $\epsilon$ -caprolactone) and the diol compound is the reaction product of two moles of 1,4-butanediol and one mole of 1,4-butanediisocyanate.
24. Drain according to claim 23, wherein the polyethyleneglycol has a molecular weight of 1000.

25. Drain according to any of the previous claims, wherein the polymer comprises a polyurethane and a polyester, polyestercarbonate or a polycarbonate, obtainable by solution blending.
26. Drain according to claim 25, wherein the polyurethane is based on a  
5 DL-lactide- $\epsilon$ -caprolactone soft segment pre-polymer and the polyester is a poly(DL-lactide- $\epsilon$ -caprolactone) copolymer.
27. Drain according to any of the previous claims, wherein said polymer is loaded with radiopaque fillers and/or pharmaceutical components such as antibiotics, anti-inflammatory agents, peptides and proteins.
- 10 28. Drain according to any of the previous claims, which is provided with perforations.
29. Nasal drain according to any of the previous claims.
30. Drain, particularly a nasal drain, according to any of the previous claims, having a wall thickness of 0.05-5.0 mm.
- 15 31. Drain according to any of the previous claims, having a total length of 3-300 mm.
32. Drain according to any of the previous claims, having an outer diameter of 0.5-50 mm.
33. Drain according to any of the previous claims, comprising a funnel  
20 shaped element on at least one end.
34. Drain according to claim 33, having a funnel length of 2-20 mm and preferably a funnel diameter of 3-30 mm.
35. Drain according to any of the previous claims, which is obtainable by dip-coating or spray coating of a polymer solution on a mandrel or extrusion of  
25 a polymer.
36. Use of a drain according to claims 21-24 used for performing coloanal anastomosis.
37. Method for treating a disorder associated with dysfunction of natural drainage of body fluids from an antrum, organ or tissue comprising  
30 introducing a drain according to any of the previous claims in said antrum,

organ or tissue, such that said antrum, organ or tissue is connected with the environment or another location within the body, after which said drain degrades over time and degradation products of said drain are cleared through the digestive channel and/or said antrum, organ or tissue and/or absorbed and subsequently metabolized and/or secreted by the body.

- 5 38. Method according to claim 37, wherein said disorder is selected from (chronic) sinusitis, inflammation of the middle ear, liver disorders, disorders of the gastro-intestinal tract, tear duct disorder, surgical wound drainage, and thoracic disorder.
- 10 39. Method according to claims 37 or 38, wherein said drain is introduced in said antrum using at least one of: sealant; suture; and staple.
40. Use of a drain according to any of the claims 1-35 in the preparation of a medicament or kit for the treatment of a disorder as defined in claims 37 or 38.